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ORIGINAL ARTICLE

The effect of adopting the IADPSG screening guidelines on the risk profile and outcomes of the gestational diabetes population

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Abstract

Objective: To compare characteristics and outcomes of women diagnosed with gestational diabetes mellitus (GDM) by the newer one-step glucose tolerance test and those diagnosed with the traditional two-step method.

Research design and methods: This was a retrospective cohort study of women with GDM who delivered in 2010–2011. Data are reported as proportion or median (interquartile range) and were compared using a Chi-square, Fisher's exact or Wilcoxon rank sum test based on data type.

Results: Of 235 women with GDM, 55.7% were diagnosed using the two-step method and 44.3% with the one-step method. The groups had similar demographics and GDM risk factors. The two-step method group was diagnosed with GDM one week later [27.0 (24.0–29.0) weeks versus 26.0 (24.0–28.0 weeks); $p = 0.13$]. The groups had similar median weight gain per week before diagnosis. After diagnosis, women in the one-step method group had significantly higher median weight gain per week [0.67 pounds/week (0.31–1.0) versus 0.56 pounds/week (0.15–0.89); $p = 0.047$]. In the one-step method group more women had suspected macrosomia (11.7% versus 5.3%, $p = 0.07$) and more neonates had a birth weight >4000 g (13.6% versus 7.5%, $p = 0.13$); however, these differences were not statistically significant. Other pregnancy and neonatal complications were similar.

Conclusions: Women diagnosed with the one-step method gained more weight per week after GDM diagnosis and had a non-statistically significant increased risk for suspected macrosomia. Our data suggest the one-step method identifies women with at least equally high risk as the two-step method.

Keywords

Diagnosis, gestational diabetes, outcomes, risk profile

History

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Introduction

The screening and diagnosis of gestational diabetes mellitus (GDM) has been the subject of much recent discussion and debate [1–6]. A number of studies have demonstrated that increasing levels of carbohydrate intolerance, even in women who were not diagnosed with GDM by customary criteria, have been associated with increased frequency of maternal–fetal complications [7–12]. Several other large randomized studies have shown that more aggressively treating ''mild'' GDM results in lower rates of adverse neonatal and maternal outcomes [13,14]. The Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) study [15] was an international, prospective study demonstrating a strong association between increasing maternal glucose levels and maternal and neonatal outcomes such as preeclampsia, cesarean delivery and large for gestational age infants.

In response to these studies, in 2010 the International Association of Diabetes in Pregnancy Study Groups (IADPSG) [16] and in 2011 the American Diabetes Association (ADA) [1] endorsed the use of universal 2-h 75-g oral glucose tolerance testing in pregnant women at 24 to 28 weeks of gestation (one-step method). Traditionally, most pregnant women were screened for GDM using a 1-h 50-g test, followed by a 3-h 100-g test if positive (two-step method). In 2011, the American Congress of Obstetricians and Gynecologists (ACOG) issued a Committee Opinion [2], which concluded that the one-step method would increase the incidence of a GDM diagnosis from approximately 8% to 18% and likely would lead to an increase in health care costs

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without definitive evidence for improvement in maternal and neonatal outcomes. This was reaffirmed in the ACOG practice bulletin on gestational diabetes in August 2013 [3]. The National Institutes of Health (NIH) held a Consensus Development Conference in March 2013, which also concluded that there is insufficient evidence to recommend the one-step method [4,5]. Later the same year, in contrast to NIH and ACOG, the Endocrine Society recommended the one-step method [6]. Even more recently, the ADA has stated that either the one-step or two-step method is acceptable for GDM screening [17].

Subsequent to the initial recommendations from IADPSG, the Joslin Diabetes Center (JDC), a freestanding center, and the academic obstetric practice at Beth Israel Deaconess Medical Center (BIDMC), a large tertiary care facility, decided to adopt the IADPSG guidelines recommended by the HAPO study and the ADA. This practice was instituted in December 2010 and has not been officially altered since the recent ACOG and NIH recommendations.

Our objective was to compare characteristics and outcomes of women diagnosed with GDM by the usual two-step method (using the National Diabetes Data Group criteria) with those diagnosed by the one-step IADPSG method. We aimed to ascertain whether patient characteristics, pregnancy management, pregnancy outcomes, and neonatal outcomes differed based on which diagnostic method was used.

Research design and methods

This was a retrospective cohort study of women with GDM and a singleton pregnancy who delivered at BIDMC from 1 January 2010 through 31 December 2011 and were seen in the JDC and BIDMC Diabetes in Pregnancy Program for GDM counseling and management. This allowed approximately one year of deliveries prior to adoption of the one-step IADPSG method and one year after. Throughout the study period, the obstetrical and endocrinology providers and dietary counseling were similar. A survey of obstetric providers at BIDMC revealed that 91% of the providers refer all the GDM patients to the JDC and BIDMC Diabetes in Pregnancy Program, indicating that the majority of GDM patients who deliver at BIDMC were identified for this study. The institutional review board at BIDMC approved this study.

We collected data from maternal and neonatal electronic medical records, including demographic characteristics, medical history, maternal weight before and during pregnancy, GDM test results, and pregnancy management (GDM treatment with diet with or without insulin and number of ultrasounds). We also obtained data on pregnancy outcomes, such as mode of delivery and maternal complications. Neonatal outcomes examined included gestational age at delivery, birth weight, need for NICU admission, hypoglycemia, hyperbilirubinemia, birth injury, clavicular fracture, or brachial plexus injury. Neonatal hypoglycemia was defined as at least one blood glucose less than 45 mg/dL. Neonatal hyperbilirubinemia was defined as treatment with phototherapy. Presence of clavicular fracture was assessed by review of radiology reports, and brachial plexus injury was defined by diagnosis of brachial plexus injury by attending neonatologist. Any neonatal adverse outcome was defined as macrosomia (birth weight >4000 g), hypoglycemia, hyperbilirubinemia, clavicle fracture, brachial plexus injury, or NICU admission.

Maternal weight within three months before pregnancy was used to calculate pre-pregnancy body mass index (BMI) and overall weight gain in pregnancy. If pre-pregnancy weight was missing, the earliest weight in the first 12 weeks of gestation was used. Data was stored in REDCap [18]. We categorized BMI as normal (18.5 to <25 kg/m^2), overweight (25.0 to <30 kg/m^2), or obese (≥ 30.0 kg/m^2), adapted from the WHO International Classification of normal, overweight, and obese adults [19]. Risk factors for GDM included a strong family history of diabetes (one first-degree relative or two second-degree relatives); being overweight or obese; chronic hypertension; polycystic ovary syndrome; being Asian, black or Hispanic; and age ≥ 35 years [3].

All data were analyzed using SAS 9.3 (SAS Institute Inc., Cary, NC). All tests were two-sided and $p < 0.05$ was required to confer significance. Comparisons were made using a Chi-square or Fisher's exact test for categorical variables and the Wilcoxon rank sum test for continuous variables. Data are reported as proportion or median (interquartile range).

Results

Of the 235 women who met eligibility criteria, 131 (55.7%) were diagnosed with GDM using the two-step method, and 104 (44.3%) were diagnosed using the one-step method. Before the one-step method was adopted, nearly all patients (98.2%) were diagnosed using the two-step method. After the new guidelines were adopted, 79.5% of the patients were diagnosed using the one-step method and the rest (20.5%) were diagnosed using the two-step method.

The two-step and one-step method groups were similar with regard to the median age, median pre-pregnancy BMI and medical history. Most (96.2%) of the patients in each group diagnosed with GDM had one risk factor for GDM ($p = 0.10$). Women in the one-step method group were more likely to be primiparous, less likely to be non-Hispanic white, and more likely to be Asian/Pacific Islander, although the differences did not reach statistical significance. Table 1 shows the maternal characteristics of the two groups.

Women in the two-step method group were diagnosed with GDM one week later in pregnancy than in the one-step method group ($p = 0.13$; Table 2). Women in both groups had a similar median weight gain per week before the GDM diagnosis. After the GDM diagnosis, the patients in the one-step method group had significantly higher median weight gain per week compared with the two-step method group ($p = 0.047$). The overall median weight gain per week was also higher in the one-step method group compared with the two-step method group (0.70 pounds/week, although this difference was not statistically significant ($p = 0.06$)). A similar proportion of the patients in each group was treated with insulin as compared to managed with diet only. None of the patients was managed using oral agents.

Both the groups delivered at a median of 39.0 weeks of gestation. Approximately half of the patients in each group delivered vaginally, and median birth weight was similar in the two groups ($p = 0.52$). Patients in the one-step method group had significantly more ultrasounds during pregnancy

Table 1. Maternal characteristics.

Characteristic	Two-step method ($n = 131$)	One-step method ($n = 104$)	p
Maternal age (years)	34.0 (32.0–37.0)	34.0 (30.0–38.0)	0.28
<35	67 (51.1)	59 (56.7)	0.39
≥35	64 (48.9)	45 (43.3)	
Body mass index before 12 weeks of gestation*	27.1 (23.2–32.5)	25.9 (22.5–31.6)	0.30
<25 (normal or underweight)	41 (35.7)	38 (42.7)	0.59
25–30 (overweight)	31 (27.0)	22 (24.7)	
≥ 30 (obese)	43 (37.4)	29 (32.6)	
Parity			0.06
Primiparous	52 (32.7)	54 (51.9)	
Multiparous	79 (60.3)	50 (48.1)	
Race/ethnicity			0.26
Non-Hispanic white	55 (42.0)	34 (32.7)	
Non-Hispanic black	18 (13.7)	13 (12.5)	
Hispanic	7 (5.3)	9 (8.7)	
Asian/Pacific Islander	36 (27.5)	40 (38.5)	
Other	15 (11.5)	8 (7.7)	
Medical history			
Family history of diabetes	61 (46.6)	50 (48.1)	0.82
Chronic hypertension	13 (9.9)	8 (7.7)	0.55
Polycystic ovary syndrome	6 (4.6)	10 (9.6)	0.13

Data are presented as median (interquartile range) or n (%).
*Data available for 115 (87.8%) women in the two-step method group and 89 (85.6%) women in the one-step method group.

Table 2. Maternal weight gain and insulin use.

	Two-step method ($n = 131$)	One-step method ($n = 104$)	p
Gestational age at time of GDM diagnosis (weeks)	27.0 (25.0–29.0)	26.0 (24.5–28.0)	0.20
Weight gain per week prior to GDM diagnosis (pounds)	0.78 (0.53–1.1)	0.81 (0.53–1.0)	0.89
Weight gain per week after GDM diagnosis (pounds)	0.56 (0.15–0.89)	0.67 (0.31–1.0)	0.047
Overall weight gain per week	0.70 (0.44–0.97)	0.79 (0.55–1.0)	0.06
Treatment			0.79
Insulin plus diet	59 (45.0)	45 (43.3)	
Diet only	72 (55.0)	59 (56.7)	

Data are presented as median (interquartile range) or n (%).

compared with patients in the two-step method group ($p = 0.003$). There were more patients who had an ultrasonographic suspicion of macrosomia in the one-step method group (11.7% versus 5.3%, $p = 0.07$) and there were more neonates with a birth weight >4000 g in the one-step method group (13.6% versus 7.5%, $p = 0.13$); however, these differences did not reach statistical significance. Other pregnancy complications, neonatal complications, and neonatal intensive care unit admission, as well as a composite measure of adverse neonatal outcomes, were not significantly different between the groups (all $p \geq 0.10$; Table 3).

Conclusions

Our study aimed to ascertain whether women diagnosed with GDM by the one-step IADPSG diagnostic method differed from those diagnosed by the two-step method with regard to patient characteristics, GDM treatment, and pregnancy and neonatal outcomes. Aside from observed differences in parity and race/ethnicity that were not statistically significant, the baseline patient characteristics and risk factors for GDM were similar in patients diagnosed with the two-step method compared with the one-step method. With the exception of slightly more weight gain per week after the GDM diagnosis and more suspected macrosomia in the one-step method group, pregnancy and neonatal outcomes did not differ based on the method of GDM diagnosis. Patients were diagnosed with GDM about a week earlier using the one-step method, probably because the extra step of the one-hour screening test was eliminated.

Although the incidence of cesarean delivery was similar between the groups, the incidence in both the groups, near 50%, was higher than what was reported for singleton and multiple gestations combined in the United States (32.8%) [20] and at our institution (37% in 2010 and 36% in 2011) during the same time period. Patients with GDM have been reported to have a higher incidence of cesarean delivery [21]; thus, this is not unexpected due to the presence of co-morbidities such as obesity and an increased risk for macrosomia.

Weight gain prior to the diagnosis of GDM was not different in the two groups. However, patients diagnosed using the one-step method gained significantly more weight per week, approximately a tenth of one pound, after the diagnosis of GDM, despite similar pre-pregnancy BMIs. This is unlikely to be a clinically significant increase in weight

Table 3. Pregnancy and neonatal outcomes.

	Two-step method ($n = 131$)	One-step method ($n = 104$)	p
Number of ultrasounds*	8.0 (5.0–11.0)	9.5 (7.0–12.0)	0.003
Gestational age at delivery (weeks)	39.0 (37.9–39.7)	39.0 (38.0–39.6)	0.99
Delivery type			0.64
Spontaneous vaginal	68 (51.9)	52 (50.0)	
Cesarean	63 (48.1)	51 (49.0)	
Vacuum-assisted vaginal	0 (0.0)	1 (1.0)	
Pregnancy complications			
Hypertensive disorder†	21 (16.0)	17 (16.3)	0.95
Polyhydramnios	1 (0.8)	2 (1.9)	0.58
IUGR	10 (7.6)	4 (3.8)	0.22
Suspected macrosomia	7 (5.3)	12 (11.5)	0.08
Shoulder dystocia	0 (0.0)	1 (1.0)	0.44
Other	14 (10.7)	5 (4.8)	0.10
Birth weight (g)	3295.0 (2995.0–3590.0)	3320.0 (2970.0–3622.5)	0.54
Weight > 4000 g	10 (7.6)	14 (13.5)	0.14
NICU Admission	23 (18.0)	12 (11.5)	0.17
Neonatal complications			
Neonatal hypoglycemia	8 (6.1)	3 (2.9)	0.35
Hyperbilirubinemia	11 (8.4)	9 (8.7)	0.94
Birth injury (clavicle fracture, brachial plexus injury)	0 (0.0)	0 (0.0)	–
Any neonatal adverse outcome‡	35 (26.7)	27 (26.0)	0.90

IUGR=intrauterine growth restriction; NICU=neonatal intensive care unit. Data are presented as median (interquartile range) or *n* (%).

*Twenty-nine (22.1%) women in the two-step method group and 22 (21.2%) in the one-step method group were missing data on the number of ultrasounds in pregnancy.

†Includes gestational hypertension, preeclampsia and hemolysis, elevated liver enzymes, low platelets.

‡Any neonatal adverse outcome includes macrosomia, hypoglycemia, birth injury, hyperbilirubinemia or NICU admission.

gain, despite being statistically significant, given that this translates to an increase in weight of only 1–2 pounds by the end of the pregnancy. It is unclear why patients in the one-step method group would have more weight gain than patients in the two-step method group after being diagnosed with GDM, but this association warrants further investigation. Nevertheless, patients in the one-step method group were also more likely to have an ultrasonographic suspicion of macrosomia before delivery as well as an infant >4000 g than the two-step method patients, although these differences were not statistically significant. Thus, the increase in weight gain may partially explain the increased risk for macrosomia seen in these patients.

It also should be noted that the patients diagnosed with the one-step method had significantly more ultrasounds than those diagnosed with the two-step method. This may explain why there were more patients with suspected fetal macrosomia in the one-step group. The difference in frequency of ultrasounds is not explained by the baseline characteristics of the two groups. We were missing data on the number of ultrasounds for more than 20% of the patients in each group, so further studies are warranted to see if this difference persists in other similar cohorts.

Strengths of this study included a diverse racial and ethnic demographic, and except for the ultrasound data mentioned above, there was very little missing data from the review of the patients' medical records. We only included patients from one academic institution in one geographic area. This can be considered as a strength of the study in that pregnancy management was fairly consistent during these two time periods, especially given that almost all GDM patients were managed by the JDC. Though it may also be considered a weakness because our findings are not necessarily generalizable to patients in other regions. The study did have several other limitations. The study population was a sample of convenience, chosen to allow for approximately one year before and after implementation of the new testing guidelines. Therefore, we did not perform an *a priori* sample size calculation. A post-hoc power calculation was performed to assess if there was enough power to detect a difference in macrosomia between the two groups. We determined that we only had 32% power to detect the difference of the observed magnitude. Thus, our sample size limited our ability to detect potentially clinically meaningful differences in outcomes between the two groups. This study was not designed to assess the expected change in GDM incidence with the one-step IADPSG method so we were not able to determine if implementing these new guidelines increased the number of women being diagnosed with GDM, which is the concern articulated by ACOG.

Our findings demonstrate that women diagnosed with GDM by the one-step method had a similarly high prevalence of GDM risk factors as women diagnosed by the two-step method. These data thus address concerns in the literature and among professional societies that the one-step IADPSG screening guidelines may identify a lower-risk group of women as having GDM, increasing their anxiety and increasing health care costs with more visits, more ultrasounds, additional laboratory testing, and no clear indication of the benefit [13,14]. In fact, patients diagnosed using the one-step method gained more weight per week after the GDM diagnosis, and had a trend towards higher risk for suspected macrosomia than the group diagnosed using the traditional two-step method. Our data suggest that the one-step IADPSG

method identifies women with at least equally high risk as the two-step method. Given that we compared different methods of diagnosis, we do not make any recommendations about clinical care based on our study. Indeed, it is important to evaluate whether treatment of women diagnosed with the one-step method will influence outcomes, and this is an aim for a future study. As additional, large-scale, multi-center studies are being done, our institution and all obstetric providers worldwide await further data and recommendations from national and international organizations.

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Declaration of interest

The authors report no conflicts of interest.

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